



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/500,293 | 10/05/2004 | Kiyoharu Oono | 2144.0220000/RWE/RAS | 9002 |
| 28393 | 7590 | 07/15/2005 | EXAMINER | |
| STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVE., N.W. WASHINGTON, DC 20005 | | | FREDMAN, JEFFREY NORMAN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |
| DATE MAILED: 07/15/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/500,293 | OONO ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey Fredman | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 June 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 is/are rejected.
- 7) Claim(s) 6 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandecki et al (U.S. Patent 6,046,003).

Regarding claim 1, Mandecki teaches a method for producing a labeled nucleic acid (e.g., fluorescently-labeled target DNA bound to probe attached to the surface of the transponder), wherein the method comprises binding the nucleic acid (e.g., oligonucleotides) to a large scale integrated circuit (e.g., solid phase particles having a transponder associated with each particle), and recording specific information (e.g., the sequence of the oligonucleotide) on the large scale integrated circuit (column 1, lines 55 - column 2, line 6, column 17, lines 28-44).

Regarding claim 1, Mandecki teaches a method for producing a labeled protein wherein the method comprises binding the protein to a large scale integrated, and recording

specific information on the large scale integrated circuit (Column 3, lines 1-27).

Regarding claim 2, Mandecki teaches wherein the specific information is characteristic to the nucleic acid (e.g., the sequence of the oligonucleotide) bound to the LSI (column 1, lines 58-60):

Regarding claim 3, Mandecki teaches a method wherein a substrate (e.g.. monoisocyanate) mediates the binding of a nucleic acid to the large scale integrated circuit (column 8, lines 21-45).

4. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon et al (U.S. Patent 6,251,595)

Regarding claim 1 , Gordon et al teach a method for producing a labeled (e.g., electronically addressed, column 6, lines 15-17) nucleic acid, wherein the method comprises binding the nucleic acid (e.g., oligonucleotides) to a large scale integrated circuit (e.g., electrode assembly, column 18, lines 1-65, column 14, lines 36-49; Fig. 2), and recording specific information on the large scale integrated circuit (column 5, lines 19-22).

Regarding claim 1 , Gordon et al teach a method for producing a labeled (e.g., electronically addressed, column 6, lines 15-17) protein, wherein the method comprises binding the protein (e.g., enzymes, column 11 , lines 51-60) to a large scale integrated circuit (e.g., electrode assembly, column 18, lines 1-65*, column 14, lines 36-49., Fig. 2), and recording specific information on the large scale integrated circuit (column 5, lines 19-22).

Regarding claim 3, Gordon et al teach a method wherein a substrate (e.g., cellulosic materials and materials derived from cellulose) mediates the binding of a nucleic acid or protein to the large scale integrated circuit (column 9, lines 35-40).

Regarding claim 4, Gordon et al teach a method wherein a cellulose vinyl acetate (e.g., cellulosic materials and materials derived from cellulose) mediates the binding of a nucleic acid or protein to the large scale integrated circuit (column 9, lines 35-40).

Regarding claim 5, Gordon et al teach a method wherein an antibody bound to a protein mediates the binding of protein to the large scale integrated circuit (e.g., antigen-antibody, column 11, lines 51-63)..

Claim Rejections - 35 USC § 103

5. The rejection of claim 6 is under 35 U.S.C. 103(a) is withdrawn in view of the amendment.

Allowable Subject Matter

6. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: Claim 6 is drawn to an embodiment with two differences from claim 1, a requirement that the protein is attached to the integrated circuit via the sugar chain and a requirement that some information regarding the sugar chain is encoded on the integrated circuit. While Keogh does teach attachment of

proteins to supports via sugar chains, Keogh does not suggest encoding this information onto an integrated circuit. While Mandecki teaches encoding the sequence of the nucleic acid onto the circuit, there is no suggestion to encode the linker information, to which the sugar in claim 6 corresponds. Therefore, there is no suggestion in the prior art to both attach a protein by a sugar chain and encode the sugar chain information onto the integrated circuit.

Response to Arguments

8. Applicant's arguments filed June 15, 2005 have been fully considered but they are not persuasive.

Applicant first argues that Mandecki does not teach a protein immobilizing a protein onto the transponder. Applicant correctly notes that PNA is simply a polyamide backbone with nucleotide bases. However, Mandecki teaches that a hapten such as biotin may be attached to the nucleic acid which is attached to the transponder (see column 3, line 17-24) and that this hapten can mediate a sandwich assay with antibodies, for example. This would result in the formation of a protein bound to the integrated circuit, meeting the limitations of the claims. Therefore, this rejection is maintained.

Applicant argues that Mandecki does not enable attachment of the nucleic acid to the solid support, except by synthesis on the support. This argument is terrifically flawed in several ways. First, Mandecki is a US patent and presumed enabled. That presumption must be rebutted by evidence, not argument. Second, the prior art is, as Applicant is almost certainly well aware, replete

Art Unit: 1637

beyond measure with methods of attachment of nucleic acids to solid supports.

This argument is particularly not persuasive.

Applicant then argues that Mandecki and Gordon do not teach attachment of "presynthesized or purified" protein or nucleic acid to the integrated circuit. This is not correct, since Mandecki does teach such an attachment at column 3, lines 36-40. Further, these elements are not a limitation of the claims and therefore this argument is moot on that ground as well.

Applicant then argues a limitation on indirect binding which finds no support in the claim or specification.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637

7/13/05